K003209

DEC - 5 2000

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Manufacturer and Contact Information:

Manufacturer – Final Product	Dade Behring Inc. Chemistry Group Route 896 P. O. Box 6101 Newark, DE 19702
Contact Information	Cathy P. Craft Dade Behring Inc. GBC Bldg 500 Mailbox 514 P.O. Box 6101 Newark, DE 19714-6101
Manufacturer – Bulk Product	Syva Company - Dade Behring Inc. 20400 Mariani Ave. Cupertino, CA 95014

2. Device Classification Name:

"Opiate test system" has been classified as Class II by the Clinical Chemistry and Clinical Toxicology Devices Panel. Reference: 21 CFR 862.3650.

3. Intended Use:

The OPI Flex® reagent cartridge used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantitative determination of opiates in human urine. Measurements obtained with the OPI method are used in the diagnosis and treatment of opiates use or overdose.

4. Device Description and Characteristics:

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Urine Opiates (OPI) Screen Flex® reagent (300 ng/mL) cartridge provides a homogenous enzyme assay intended for use in qualitative and semiquantitative analysis of opiates in human urine. The OPI method has been found to be substantially equivalent to the predicate device: Syva Emit® II Plus Opiates 300 ng/mL Assay with regard to intended use, assay sample, and overall performance characteristics.

K003209

Comparative Analysis

The Dimension® OPI method showed very good correlation to the Syva Emit® II Plus Opiates Assay (comparative method) for qualitative analysis. One hundred fifteen (115) specimens were tested. Sixty (60) samples were positive and forty-eight (48) samples were negative by both methods. The agreement between the OPI method and the comparative method using the 300 ng/mL cutoff result was 94%. Seven (7) discordant samples were positive by the OPI method and negative by the Syva Emit® II Plus method. Note that all seven (7) specimens had values that were very near the cutoff (303 to 318 ng/mL). These discrepant results are listed below.

Discrepant specimens (ng/mL):

Dimension® RxL	Syva Emit® II Plus	GC/MS
312	298	54/100 (Morphine/Codeine)
303	255	184 (Codeine only)
308	282	26/233 (Morphine/Codeine)
318	288	40/120 (Morphine/Codeine)
307	279	28/164 (Morphine/Codeine)
312	290	33/117 (Morphine/Codeine)
315	297	183 (Codeine only)

All positive samples and a portion of negative samples (n=22), as assessed by the OPI method, were analyzed by GC/MS for confirmatory purposes. The comparative analyses demonstrated a good relationship between the semiquantitative analyses and GC/MS values.

Spiked Sample Recovery

The qualitative and semiquantitative attributes were assessed by determining the accuracy of recovery for the analyte in spiked samples by the OPI method.

For the qualitative method, known levels of morphine, spiked at levels less than or equal to minus 10% of the 300 ng/mL cutoff (0 – 270 ng/mL) and spiked levels greater than or equal to plus 10% of the 300 ng/mL cutoff (330 – 2000 ng/mL) were consistently distinguished as negative or positive.

The semiquantitative results for known spiked concentrations for the OPI method quantitated within 13% of the nominal concentration between 50 and 1800 ng/mL.

Precision

A precision study was performed on the 300 ng/mL cutoff level and controls of +/-25% of the cutoff using the Dimension® OPI method in the semiquantitative mode. Acceptable within run and total precision statistics in the semiquantitative assay were observed.

K003209

In the semiquantitative mode the within run precision demonstrated coefficients of variation (%CV) for controls and cutoff concentrations ranging from 2.0 to 4.1% and for total precision %CV ranging from 4.1 to 7.8%.

5. **Substantial Equivalence:**
In conclusion, Dade Behring Inc. considers the Urine Opiates (OPI) Screen Flex® reagent cartridge to be substantially equivalent to the Syva Emit® II Plus Opiates Assay with regard to intended use, assay sample, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 5 2000

Ms. Cathy P. Craft
Group Manager RA
Dade Behring, Inc.
Glasgow Business Community
PO Box 6101
Building 500
Newark, Delaware 19714

Re: K003209
Trade Name: Urine Opiates (OPI) Screen Flex® Reagent Cartridge
Regulatory Class: II
Product Code: DJG
Dated: October 11, 2000
Received: October 13, 2000

Dear Ms. Craft:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K003209

Device Name: Urine Opiates (OPI) Screen Flex® reagent cartridge

Indications for Use:

The OPI Flex® reagent cartridge (300 ng/mLcutoff) used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantitative determination of opiates in human urine. Measurements obtained with the OPI method are used in the diagnosis and treatment of opiates use or overdose.

Sean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003209

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)